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No. 98-___

IN THE
SUPREME COURT OF THE UNITED STATES
October Term, 1998

VITEK SUPPLY CORPORATION and
JANNES DOPPENBERG,

Petitioners,

vs.

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. Whether omission from the jury instructions of a necessary element of the charged offense is rendered harmless by evidence at trial and arguments of counsel.

2. Whether a trial court may reject as "untimely" a request for a proper lesser-included offense instruction made orally during the jury instructions conference.

3. In assessing "loss" under the Sentencing Guideline for fraud, U.S.S.G. §2F1.1, which party must bear the burden of proof regarding whether the alleged victim's "loss" is imputable to the defendant?

PARTIES IN COURT BELOW

Other than the present Petitioners and Respondent, there were no other parties in the Court of Appeals.

The parent company of Vitek Supply Corporation is Nutritional Products & Services, Inc. Vitek has no non-wholly owned subsidiaries.

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

Petitioners Vitek Supply Corporation and Jannes Doppenberg respectfully request that the Court issue a writ of certiorari to review the judgment of the United States Court of Appeals affirming the judgments of conviction and

sentences against them.

OPINIONS BELOW

The opinion of the court of appeals, *United States v. Vitek Supply Corp.*, 144 F.3d 476 (7th Cir. 1998), is in Appendix A. The unpublished order of that court denying reconsideration is in Appendix B.

JURISDICTION

The court of appeals entered judgment on May 14, 1998, and denied the petitioner's timely request for rehearing of that decision on June 16, 1998. This Court's jurisdiction is invoked under 28 U.S.C. §1254(1) and Supreme Court Rule 13.3.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This petition concerns the construction and application of Fed. R. Crim. P. 30, which provides as follows:

> **Rule 30. Instructions**
>
> At the close of the evidence or at such earlier time during the trial as the court reasonably directs, any party may file written requests that the court instruct the jury on the law as set forth in the requests. At the same time copies of such

> requests shall be furnished to all parties. The court shall inform counsel of its proposed action upon the requests prior to their arguments to the jury. The court may instruct the jury before or after the arguments are completed or at both times. No party may assign as error any portion of the charge or omission therefrom unless that party objects thereto before the jury retires to consider its verdict, stating distinctly the matter to which that party objects and the grounds of the objection. Opportunity shall be given to make the objection out of the hearing of the jury and, on request of any party, out of the presence of the jury.

This petition also involves the construction and application of U.S.S.G. §2F1.1(a) & (b):

> **§2F1.1 Fraud and Deceit: Forgery: Offenses Involving Altered or Counterfeit Instruments Other than Counterfeit Bearer Obligations of the United States**
>
> (a) Base Offense Level: 6
>
> (b) Specific Offense Characteristics
>
> (1) If the loss exceeded $2,000, increase the offense level as follows:

Loss (Apply the Greatest)	Increase in Level
(A) $2,000 or less	no increase
(B) More than $2,000	add 1
(C) More than $5,000	add 2

(D) More than $10,000	add 3
(E) More than $20,000	add 4
(F) More than $40,000	add 5
(G) More than $70,000	add 6
(H) More than $120,000	add 7
(I) More than $200,000	add 8
(J) More than $350,000	add 9
(K) More than $500,000	add 10

* * *

STATEMENT OF THE CASE

The superseding indictment in this case charged Jannes Doppenberg and Vitek Supply Corporation in each of 12 counts. Count 1 charged a conspiracy to defraud the United States, specifically the United States Customs Service and the United States Food & Drug Administration. Counts 2 through 6 charged smuggling offenses. Counts 7 through 12 charged shipments in interstate commerce of misbranded and adulterated drugs. (R45).[1]

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[1] A third defendant, Vitek office manager Sherry Steffen, was charged in three of the counts and pled guilty before trial to one count of misdemeanor conspiracy. Tr. 2096-98. She was not involved in (continued...)

Vitek imported animal feeds and the ingredients for animal feeds (often referred to as premixes or pre-premixes, depending on the rounds of blending that would later occur) (Tr. 1633-37, 1649-50). Jannes Doppenberg was the manager and, later, the president of Vitek (Tr. 1631).

The government claimed that certain substances imported by Vitek and resold to its customers -- clenbuterol, avoparcine, zinc bacitracin, and NFZ -- constituted "drugs" under federal law (Tr. 272-74). Although, under the government's theory, Vitek's customers knew what they were receiving and wanted these unapproved drugs (Tr. 3864-65, 3868-69), Vitek could not legally import and redistribute these items. Vitek, charged the government, imported these substances through false invoices, and then sold them to its customers without identifying them on the product labels. Additionally, charged the government, Vitek imported animal

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[1](...continued)
this appeal.

feeds containing vitamins, which were lawful products; but Vitek fraudulently escaped paying the proper duty on these animal feeds.

The jury trial, the Honorable Thomas J. Curran presiding, began on May 6, 1997 and lasted five weeks. There was lengthy testimony both on the regulatory programs of the FDA whose mission the defendants allegedly stymied and on the government's laboratory testing of the questioned substances. There was also lengthy testimony on the preparation and shipping of specific batches of animal feeds and premixes. Appellants will attempt to present a concise and balanced outline of this evidence.

In February of 1994, a cargo container of imported goods arrived in Milwaukee for delivery to Vitek (Tr. 534). This cargo container was shipped by the Pricor Company of the Netherlands (Tr. 535), Vitek's parent company and a principal supplier of Vitek's imported ingredients (Tr. 1650). The Customs Service opened that container for inspection.

During this inspection, Customs agents discovered packages hidden in the middle of the declared cargo (Tr. 546). These packages bore labels for the following substances: oxytetracycline hydrochloride, choline sulfate, furazolidone hydrochloride, and baytril (Tr. 549-50). The furazolidone hydrochloride was not listed on the Customs entry papers for this particular shipment (Tr. 553) and became the basis of Count 6 of the superseding indictment.

After this inspection, the cargo container was repacked and delivered three days later to Vitek. A special agent of the Customs Service obtained a search warrant for the Vitek premises (Tr. 537), and this warrant was executed shortly after the cargo container was delivered to Vitek.

In addition to quantities of animal feeds, the searching agents seized approximately 20 banker's boxes of Vitek's books and records, These records included inventories, production formulas, production records, and shipping documents. The agents also confiscated Vitek's computer system,

including all data disks (R59:Exh.B, at 1).

Doppenberg was present during the search and he was questioned by the agents. He produced a handwritten statement, Exhibit 380, in which he admitted that (1) Vitek had mixed a "repartitioning agent" into a product called "lamb premix," which had an ingredient number of 107; (2) the current shipment in the cargo container contained zinc bacitracin; and (3) on a previous occasion, avoparcine had been brought into the country by Vitek. Doppenberg allegedly made oral admissions that the company's records referred to clenbuterol as ingredient 107; avoparcine, as ingredient 107A; and zinc bacitracin, as ingredient number 64 (Tr. 574-75).

Two Vitek employees testified concerning the receipt of imported substances and the distribution by Vitek to its customers of blended animal feeds. Jerry Kikkert, the plant foreman, supervised receiving ingredients, blending them into animal feeds and premixes, and then shipping the blended

products to the customers (Tr. 935, 1103-04). On seven or eight occasions, he received shipments from Holland that had hidden packages much like the packages discovered in February of 1994 (Tr. 989). These items would be set aside and later sent to a Vitek customer known as VIV (Tr. 991).

When imported goods were delivered at Vitek, Kikkert would unload the shipment and make a record of what was received (Tr. 1104). He recounted several instances in which the labels on the imported bags of premix differed from the description in the freight documents (Tr. 1107-16). He acknowledged that he had no way of knowing what ingredients were in any of the products, and that an outside laboratory had the responsibility to run analyses of the products (Tr. 1147).

Kikkert also testified that Vitek received bags of avotan (a mixture containing avoparcine) and bags of zinc bacitracin (Tr. 994, 1099). These substances were then mixed into various animal feeds. These substances would not

always be part of the typed production formulas given to him. Instead, if a mixing required one of these substances, a post-it style note, placed on the written production order, would direct him to add these ingredients into a particular batch. (Tr. 1161).

Kikkert believed that when a formula called for "ingredient 107," he would see a post-it note telling him to mix in lamb premix (Tr. 954-55). In the late 1980's, Vitek imported a product called lamb premix from Holland (Tr. 971). In 1992, Kikkert produced a product called lamb premix by mixing with other ingredients an ingredient given to him by Doppenberg in a small plastic sandwich bag (Tr. 1093). Doppenberg, according to Kikkert, claimed to have obtained the contents of the sandwich bag from Mr. Hoogendyjk, a gentleman associated with Pricor in Holland (Tr. 1097).

Kikkert also recalled making blends with "ingredient 64," which written production formulas called zinc chelate.

Kikkert thought zinc chelate was another name for zinc bacitracin (Tr. 993). Sometimes, a post-it note would tell him to substitute zinc bacitracin for another ingredient (Tr. 995).

Sherry Steffen was the office manager at Vitek and had been charged in the superseding indictment. She pleaded guilty to a misdemeanor conspiracy to violate federal pure food and drug laws and testified at trial pursuant to a plea agreement (Tr. 2096). Her duties at Vitek required that she place orders with Pricor in Holland (Tr. 1649-50). She gave Kikkert the production formulas for specific batches of animal feeds to be blended (Tr. 1639-40). She took orders from Vitek's customers, billed the customers, and arranged for the transportation of shipments to them (Tr. 1637-38, 1646-47). She did not design the formulas, and believed that only Doppenberg devised the formulas for Vitek's animal feeds (Tr. 1807-08). Steffen used post-it notes when necessary to tell Kikkert to substitute something for a typed ingredient on

a production formula (Tr. 2325).

Steffen also testified to Vitek's regularly writing customers about the positive effects of animal feeds containing avoparcine and zinc bacitracin. Customers ordered products containing these substances, and were billed for them on invoices that specifically identified avoparcine and zinc bacitracin. These two ingredients were openly identified in correspondence and in customer records, and no effort was made to destroy such records or correspondence. (Tr. 2150-59, 2161-66, 2191-92, 2194-96).

Moreover, FDA inspectors visited Vitek for unannounced inspections prior to the search warrant and were allowed access to any and all Vitek records. Written inventories listed avoparcine and zinc bacitracin as being present at the Vitek facility, and the inspectors were allowed to peruse Vitek's written inventories (Tr. 2192-93). An FDA inspector confirmed this testimony by Steffen (Tr. 3607).

Steffen also testified to an episode in which

Doppenberg informed Vitek's Custom's broker that an item imported by Vitek was not, as the Customs Service believed, duty-free, but was subject to duty. After this correspondence, Customs billed Vitek for duty on this product (Tr. 2133-38).

An FDA official testified as to the regulatory status of avoparcine, zinc bacitracin, clenbuterol, and NFZ. None of these four substances was subject to an approved new animal drug application for use in veal calves during the relevant time period (Tr. 1236-37, 1250, 1264, 1265). *See* 21 U.S.C. §360b. A new animal drug application is required only if the substance in question is indeed a new drug in the statutory sense (Tr. 1277). The witness did not testify that any of these four substances was indeed a drug or new animal drug as those terms are used in the statute. *See* Tr. 1230. She did testify, however, that clenbuterol and avoparcine altered bodily functions (Tr. 1231, 1250). She further testified that, if a label on an animal feed for veal calves were to identify any one of these four substances as an ingredient, the FDA

would scrutinize that product and would probably institute an investigation (Tr. 1266-67).

Chemists from the FDA laboratory in Cincinnati testified that they had performed tests in an effort to establish the chemical identity of various substances obtained from Vitek and from Vitek's customers. These chemists rendered opinions that their test results were "consistent" with the presence of the alleged illegal substances in the Vitek products (Tr. 2967, 2986, 3030, 3034).

On June 7, 1996, the jury convicted both defendants of all 12 counts in the indictment. Following four days of sentencing hearings, the district court sentenced the defendants on January 21, 1997, and entered judgments on January 27, 1997 (R182, 184).

The defendants timely filed their notices of appeal and, on May 14, 1998, the Seventh Circuit Court of Appeals affirmed the convictions and sentences (App. A). *United States v. Vitek Supply Corp.*, 144 F.3d 476 (7th Cir. 1998).

On June 16, 1998, that Court denied the defendants' timely-filed petition for rehearing (App. B).

The court of appeals had jurisdiction to hear this appeal from final judgments of conviction and sentence under 18 U.S.C. §3742(a) and 28 U.S.C. §1291.

REASONS FOR ALLOWANCE OF THE WRIT

I.

SUPREME COURT REVIEW IS APPROPRIATE TO DETERMINE WHETHER THE JURY INSTRUCTIONS' OMISSION OF A NECESSARY ELEMENT OF THE CHARGED OFFENSE IS RENDERED HARMLESS BY EVIDENCE AT TRIAL AND ARGUMENTS OF COUNSEL.

Counts Seven, Nine, Eleven and Twelve charged Vitek and Doppenberg with introducing misbranded drugs (*i.e.*, drugs with false or misleading labels, *see* 21 U.S.C. §352) in interstate commerce in violation of 21 U.S.C. §333(a)(2). Counts Eight and Ten charged them with introducing adulterated drugs in interstate commerce, also in violation of §333(a)(2). The indictment alleged that the drugs were "adulterated" because they were "new animal drugs" -- that they had not been approved by the FDA and recognized as

safe and effective for their intended use of promoting growth and feed efficiency in veal calves. In order to be guilty of Counts Seven to Twelve, the defendants had to have acted with "intent to defraud or mislead." 21 U.S.C. §333(a)(2). To act with this intent, Vitek and Doppenberg must have had "knowledge of the essential nature of the alleged fraud." *United States v. Hiland*, 909 F.2d 1114, 1128 (8th Cir. 1990).

The defendants below steadfastly maintained that for a felony violation of 21 U.S.C. §333(a)(2) the government must prove that they had knowledge that the substance claimed to be a drug was intended to affect the structure and function of the body, but was not food,[2] and, further, that in the case of the adulteration counts (Counts 8 and 10) the substance was not recognized among experts as safe and effective.[3]

The defendants objected to the government's proposed instructions, since they omitted this knowledge requirement (Tr. 3722). They proposed their own instructions on knowledge applicable to Counts 7-12 (R106:Nos. 3, 9; R114:No. 77). The court gave the government's instruction, and rejected the defendants' proposed instructions (Tr. 3762, 3764, 3804).

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[2] 21 U.S.C. §321(g)(1).

[3] 21 U.S.C. 321(v)(1).

The Court of Appeals acknowledged that knowledge was required for conviction:

> Given the allegations against Vitek and Doppenberg, the government needed to show that the defendants: (1) knew they were distributing a "new animal drug"; and (2) knew their labeling omitted any mention of unapproved substances. *See Hiland*, 909 F.2d at 1128; *United States v. Industrial Lab. Co.*, 456 F.2d 908, 910 (10th Cir. 1972).

(App. A:16). That Court likewise acknowledged that the district court's instructions failed to include these necessary elements of the offenses charged (App. A:16-17). The Court concluded, however, that the defendants were not prejudiced by this omission in light of the "larger context," consisting of the evidence presented at trial and the closing arguments of counsel:

> In light of these closing arguments and the evidence presented at trial, the jury understood that one of the issues was whether Vitek and Doppenberg *knew* that they were distributing "new animal drugs" and that their labeling omitted information about the presence of unapproved substances.

(App. A:17).

This Court has recognized that the jury instructions must protect a criminal defendant's "right to have a jury

determine, beyond a reasonable doubt, his guilt of every element of the crime with which he is charged." *United States v. Gaudin*, 515 U.S. 506, 522-23 (1995). As recently as 1986, a majority of this Court adhered to the view that "a jury's verdict cannot stand if the instructions provided the jury do not require it to find each element of the crime under the proper standard of proof." *Cabana v. Bullock*, 474 U.S. 376, 384 (1986). *See also Carpenters v. United States*, 330 U.S. 395, 408-09 (1947).

More recent decisions, however, have held that constitutionally invalid jury instructions remain subject to harmless error analysis. *See Yates v. Evatt*, 500 U.S. 391, 402 (1991) (taint of an unconstitutional burden-shifting instruction subject to harmless error analysis);[4] *Carella v. California*, 491 U.S. 263, 266 (1989) (*per curiam*) (instruction containing an erroneous mandatory presumption subject to harmless error analysis); *Pope v. Illinois*, 481 U.S. 497, 502-04 (1987) (instruction misstating element of an offense subject to harmless error analysis); *Rose v. Clark*, 478 U.S. 570, 581-82 (1986) (instruction containing erroneous rebuttable presumption subject to harmless error analysis).

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[4] *Yates* was disapproved on other grounds in *Estelle v. McGuire*, 502 U.S. 62, 73 n.4 (1991).

The question remains, however, regarding the proper scope of harmless error review where, as here, the instructions omit an essential element of the charged offense. The Court suggests in *Pope* and *Rose* that the deciding factor is whether, under the instructions given, the jury necessarily found facts which conclusively establish the omitted or misdescribed element as well. *Pope* 481 U.S. at 503; *Rose*, 478 U.S. at 580-81.

The Court below, however, focused not on what the jury necessarily found under the trial court's instructions, but on what the jury might have assumed would be in issue in light of the evidence and arguments of counsel (App. A:17). In other words, that Court assumed that the jury would require proof of knowledge beyond a reasonable doubt, despite the omission of such an element from the instructions.

The question for the Court, therefore, is whether constitutionally defective jury instructions may be rendered harmless based upon what issues, omitted from the instructions, may be suggested by the evidence and arguments of counsel. The Court previously held that "arguments of counsel cannot substitute for instructions by the court," *Taylor v.*

Kentucky, 436 U.S. 478, 488-89 (1978),[5] but that was before the Court's recent decisions applying harmless error analysis to jury instructions.

Because the Court of Appeals' decision addresses an important federal question of continuing importance, and because that decision is directly contrary to this Court's decision in *Taylor*, review by this Court is appropriate to determine the applicable standard and the continuing validity of *Taylor*. *See* Sup. Ct. R. 10(a) & (c).

Petitioners also note that the Court granted certiorari just last term on a similar issue but was forced to dismiss the writ as improvidently granted after finding that the question was not fairly presented by the record. *See Rogers v. United States*, 522 U.S. ___, 118 S.Ct. 673 (1998). The question which the Court there found to justify review was whether a district court's failure to instruct the jury on an element of the

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[5] Oddly enough, the Seventh Circuit in this case overlooked its own authority to the same effect. *See United States v. Capas*, 29 F.3d 1187, 1194 (7th Cir. 1994) ("[T]he testimony of witnesses and arguments advanced by counsel may well be ignored by the jury"); *United States v. Walters*, 913 F.2d 388, 392 (7th Cir. 1990); *United States v. Phillips*, 217 F.2d 435, 440 (7th Cir. 1954) (Argument to a jury on a legal issue unsupported by an instruction to which the defendant is entitled "constitutes an aggravation rather than a mitigation of the harmful effect of the court's refusal to instruct").

offense is harmless where, at trial, the defendant admitted that element.

II.

SUPREME COURT REVIEW IS APPROPRIATE TO DETERMINE WHETHER A TRIAL COURT MAY REJECT AS "UNTIMELY" A REQUEST FOR A PROPER LESSER-INCLUDED OFFENSE INSTRUCTION MADE ORALLY DURING THE JURY INSTRUCTIONS CONFERENCE.

The defendants in counts seven through twelve were charged with violations of 21 U.S.C. §331(a)(2), shipping adulterated and misbranded drugs in interstate commence. Under 21 U.S.C. §333(a)(1), this conduct is a misdemeanor. However, under 21 U.S.C. §333(a)(2), this conduct is a felony if the defendant acts "with the intent to defraud or mislead." The misdemeanor and felony offenses have the same elements, except for the added element of intent to defraud that is an element of the felony offense.

Federal Rule of Criminal Procedure 31(c) allows a defendant to be convicted of "an offense necessarily included in the offense charged." An offense is a lesser offense when "the elements of the lesser offense are a sub-set of the elements of the charged offense." *Schmuck v. United States*, 489 U.S. 705, 716 (1989). The trial court must look at the

statutory elements of both offenses. The offense with the lesser punishment must require fewer elements than the greater offense, but it may not add any elements to those required for conviction under the greater offense.

Because the only difference between the misdemeanor and the felony is the additional element of "intent to defraud or mislead" in the felony, Section 333(a)(1) is clearly a lesser offense within Section 333(a)(2).

A lesser-included offense must be submitted to the jury whenever a rational trier of fact could have found the defendant innocent of the greater offense, but guilty of the lesser offense. *Keeble v. United States*, 412 U.S. 205, 208 (1973).

Counsel for Doppenberg requested lesser-included offense instructions during the jury instructions conference when its became apparent that the trial court did not intend to submit lesser offense verdicts (Tr. 3835).[6] This request was made orally some two hours before the government started its summation and before the Court submitted to counsel its final draft of the instructions it intended to give

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[6] The Court previously had agreed that objections to instructions and submissions of requested instructions by one defendant would be considered as made by both (Tr. 3724).

(Tr. 3835).[7] The court nonetheless denied the request as untimely (Tr. 3835).

Defense counsel, during the government's summation, submitted in written form their earlier oral request for lesser-included offense instructions (Tr. 3925; R123:11; Defendant's Requested Instruction No. 151). The trial court declined to give the lesser-included offense instructions on the ground that the request was not timely (Trans. 3928).

The Court of Appeals affirmed the convictions on these counts on the grounds that the request for lesser-included offense instructions was not timely, because it had not been made in writing until after the government began its closing arguments (App. A:15 n.2).

Although Fed. R. Crim. P. 30 "evidences a preference for written requests for instructions," *United States v. Krapp*, 815 F.2d 1183, 1187 (8th Cir.), *cert. denied*, 484 U.S. 860

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[7] The record reflects that, prior to the conclusion of the instruction conference at 8:34AM, the defendant requested that lesser included offenses be submitted to the jury. (Tr. 3835). The government commenced its summation at 10:49AM and finished at 2:48PM. (Trans. 3837, 3919).

The only order concerning jury instructions required that they be submitted prior to trial. This order was not consistent with Rule 30, Fed. R. Crim. P. and both the government and the defendants submitted proposed instructions during trial. (*See e.g.* Trans. 3704).

(1987), that preference has not been read as a rigid bar to oral requests. *E.g.*, *id.* The Seventh Circuit's decision to the contrary directly conflicts with the holdings of other circuits to the effect that an oral request for lesser-included offense or other instructions is sufficient to alert the trial judge to the necessity for the inclusion of the lesser verdicts and preserves the request for appellate review. *Krapp*, 815 F.2d at 1187; *United States v. Whitaker*, 447 F.2d 314, 317 (D.C. Cir. 1971).[8]

Because the court of appeals' decision on this question conflicts with the decisions of at least two other federal courts, and because that courts' analysis of that important federal question is at odds with the stated purpose of the federal rules to "secure . . . fairness in administration" and to "provide for the just determination of every criminal proceeding," this case presents the type of compelling reasons generally required for the grant of certiorari. *See* Sup. Ct. R. 10(a) & (c).

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[8] In holding that the defendant's request for lesser-included offense instructions was not timely because it was made after the prosecution began it summation, the Court relied on *United States v. Watson*, 894 F.2d 1345 (D.C. Cir. 1990). *Watson* is not apposite. In *Watson*, the lesser-included offense instruction was not requested until after both parties had delivered their summations.

III.

SUPREME COURT REVIEW IS APPROPRIATE TO DETERMINE WHO BEARS THE BURDEN OF PROOF REGARDING "LOSS" UNDER U.S.S.G. §2F1.1.

Pursuant to U.S.S.G. §2F1.1(b)(1), the base offense level of 6 in a fraud case is adjusted upward "[i]f the loss exceeded $2,000." The trial court here enhanced the petitioners' guidelines offense level 10 points under this provision, based upon a finding of $735,267 of "loss." $705,814 of that figure represented the value of veal calves owned by Joanne's Swiss Class Raisers and the related Swissland Packing Co. (jointly "Joanne's" or "Swissland"), these calves having been destroyed after the FDA learned that they may have been fed furazolidone.

Joanne's and Swissland raised and processed veal calves into meat for human consumption. Over a period of many years, they retained the services of American Feed and Livestock ("AF&L") and Dr. Daniel Shields to provide food and nutrients for the calves and to find growers to run the barns. (R205:22-23, 32-33, 41-42, 46).

In 1994, the FDA asserted that Shields had treated scours in some of Joanne's calves with a product called Apple First Start, which he had obtained from the defendants and

which the government claims contained an illegal nitrofuran (a/k/a "NFZ"), known as furazolidone (R205:16-18).[9] While a panel of experts hired by Joanne's determined that the meat from at least five of the herds was perfectly safe for human consumption and the U.S. Department of Agriculture approved its sale for that purpose (*id.*:66-68; R176:Exhs.D-A, D-B, D-C), the FDA nonetheless assumed the meat was "adulterated" and objected to the sale (R205:62-63, 65). Rather than run the risk of prosecution by selling the meat, Joanne's chose simply to destroy it (R205:65).

As conceded by Joanne's attorney at the sentencing hearing, Joanne's received a warning letter from the FDA documenting a history of misusing animal drugs in its veal raising operations (R205:74-76). Copies of that warning letter dated November 29, 1995, and a follow-up letter dated March 6, 1996, showed not merely inaccurate recordkeeping, but that Joanne's also used at least seven animal drugs in veal calves contrary to their approved labeling, as well as one, metronidazole, which is a carcinogen and has never been approved for use in food producing animals (R176:Exhs.D-E

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[9] Although previously approved for some animal feeds, nitrofurans were banned in 1991 after the FDA found that the proponents of the medication failed to prove its safety. 91 Fed. Reg. 41902-12 (August 23, 1991).

& D-F).

Evidence also demonstrated that Joanne's itself knowingly maintained nitrofurans, specifically NFZ, in inventory and distributed it to its growers at least as late as mid-1993, despite the fact it was banned for all purposes on August 23, 1991. *See* 91 Fed. Reg. 41902-12. The defendants submitted to the court copies of various Swissland and Joanne's inventories, memoranda, and medication distribution forms the defendants had received from the government which reflected Joanne's use of NFZ over an extended period of time (R176:Exh.D-G4).

Finally on this point, the defendants subpoenaed the owners of Joanne's and their employee, a Mr. Krones, to testify at the sentencing hearing. They all moved the court to quash the defendants' subpoenas, arguing in part that they likely would assert their Fifth Amendment privileges when questioned about their claimed losses. (R163:6 n.1; R166:2).

Over defense objection, the government sought to include as "losses" under §2F1.1(b)(1) the cost of the destroyed animals, Joanne's "lost profits," and certain consequential damages, totalling $1,277,738.30 (3rd attachment to Addendum to Doppenberg PSI; R149:13-14 & Exh.D; R205:15-19). Following extensive briefing and argument on the issue (R145:9-13; R147:9-13; R175:1-4; R176; R178:1-3;

R205:15-78; R236; R237:168-208), the court rejected the claim for lost profits and consequential damages, as well as the costs attributable to animals which died from natural causes (R237:207-11). While the government conceded, and the court determined, that the defendants did not intend to cause a loss to Joanne's (R237:220-22), the court nonetheless included as "losses" the $705,814 cost of the animals which Joanne's ultimately destroyed (R237:208-210).

Prior to this case, the lower courts, including the Seventh Circuit, consistently have held that the government has the burden of proving inclusion of any alleged loss by a preponderance of the evidence. *E.g.*, *United States v. Haddock*, 12 F.3d 950, 961 (10th Cir. 1993).[10] Mere assumptions and conclusory accusations are insufficient as a matter of law. *E.g.*, *United States v. Andersen*, 45 F.3d 217, 220-22 (7th Cir. 1995).

Yet, all the government submitted to the sentencing court was a conclusory allegation that Joanne's destroyed

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[10] *See also United States v. Dabbs*, 134 F.3d 1071, 1081 (11th Cir.), *rehr'g denied*, 144 F.3d 57 (11th Cir. 1998); *United States v. Wells*, 127 F.3d 739, 745 (8th Cir. 1997); *United States v. Barnes*, 125 F.3d 1287, 1290 (9th Cir. 1997); *United States v. Egemonye*, 62 F.3d 425, 428-29 (1st Cir. 1995); *United States v. Leonzo*, 50 F.3d 1086, 1087-88 (D.C. Cir. 1995); *United States v. Reese*, 33 F.3d 166, 174 (2d Cir. 1994), *cert. denied*, 513 U.S. 1092 (1995).

certain meat which may have been "adulterated" with nitrofurans and a claim by Joanne's that it was therefore entitled to $1,277,738.30. The government failed to present any evidence (1) that Joanne's was in any way defrauded or misled into feeding nitrofurans to its calves, or (2) that either of the defendants acted or conspired to defraud or mislead Joanne's into feeding nitrofurans to its calves.

The government admitted below that Joanne's "losses" could not be included under the Guidelines if it knew its calves were being fed nitrofurans (R178:2), and conceded on appeal that it had not affirmatively proven that Joanne's was defrauded by the defendants. Gov't Brief at 55. Instead, it argued that it should not have to meet that "onerous burden" and sought to shift the burden of proof to the defendants:

> The government submits that it meets its overall burden of proof by demonstrating loss to a third party caused by the defendants' crimes, together with the absence of any evidence that the third party knew of the crime and accepted its benefits.

Id.[11] The Court of Appeals implicitly adopted this argument,

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[11] The government could have called Joanne's officers as witnesses if they in fact would have supported its claim, but it chose not to do so. Indeed, it failed to present *any* evidence that Joanne's was (continued...)

as it summarily concluded that the trial court's inclusion of Joanne's losses was not clearly erroneous (App. A:20 n.3).

The Court of Appeals here thus placed itself directly in conflict with every other appellate court to have considered the burden of proof in attributing alleged "losses" to defendants under the Guidelines. Review accordingly is appropri-

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[11](...continued)
misled or lacked knowledge that it was continuing its practice of feeding its calves nitrofurans. The record thus fails to provide any rational basis for concluding that Joanne's was a victim of fraud rather than a knowing participant. For the same reasons, the government failed to prove that destruction of the calves was "caused by the defendants' crimes," rather than by Joanne's getting caught red-handed.

The record is replete, on the other hand, with uncontroverted evidence that Joanne's knew full well what it was getting for its money and that it was more than willing to misuse NFZs and other animal drugs to keep its calves healthy. Nitrofurans *never* were authorized for use in veal calves (Tr. 1262-63; GX394), so this was not a case of Joanne's "us[ing] up" a previously legal stockpile of drugs. GB:56. Indeed, Joanne's employees knowingly distributed NFZ to its growers for at least two years after it was banned for *any* purpose (R176:Exh.D-G4).

The only question, therefore, was whether Joanne's also knew that its employees continued to use nitrofurans in its calves when, in the fall of 1993, the term "NFZ" on its distribution orders was replaced with "Apple First Start," a product created by its agent, Dr. Dan Shields (*See* Tr. 1060-63). Nothing in the record suggests that Joanne's suddenly decided to "go straight" and stop using the illegal NFZs it had knowingly used for so long to keep its calves healthy. It certainly did not stop using other illegal drugs on its calves (R176:Exhs.D-E & D-F). Rather, the inference is inescapable that Joanne's knew exactly what it was doing.

ate under S. Ct. R. 10(a) & (c).

CONCLUSION

For the reasons stated, the Court should grant a writ of certiorari to review the decision of the court of appeals.

Dated at Milwaukee, Wisconsin, September 14, 1998.

Respectfully submitted,

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APPENDIX A

In the
United States Court of Appeals
For the Seventh Circuit

Nos. 97-1254, 97-1255 & 97-1498

UNITED STATES OF AMERICA,

Plaintiff-Appellee, Cross-Appellant,

v.

VITEK SUPPLY CORPORATION
and JANNES DOPPENBERG,

Defendants-Appellants, Cross-Appellees.

Appeal from the United States District Court
for the Eastern District of Wisconsin.
No. 95-CR-221—**Thomas J. Curran**, *Judge*.

ARGUED OCTOBER 8, 1997—DECIDED MAY 14, 1998

Before CUDAHY, COFFEY, and EVANS, *Circuit Judges*.

CUDAHY, *Circuit Judge*. Vitek Supply Corporation manufactured "premixes" for veal calves—that is, mixtures that feed companies and livestock growers add to animal feed. Certain premixes contained clenbuterol, avoparcine, zinc bacitracin or various nitrofurans. Some of these substances promote growth and increase meat-to-fat ratios; others treat and prevent scours (diarrhea). And they are all unapproved by the Food and Drug Administration (FDA), either for use in food-producing animals generally or veal calves specifically. Several of the drugs are carcinogens; one may lead to acute poisoning in humans; and another may increase human resistance to antibiotics.

Vitek smuggled these drugs into the United States with the help of its Dutch parent, Pricor B.V. In shipments from Pricor to Vitek, the companies either misdescribed the drugs in documents submitted to the United States Customs Service or failed to declare the substances altogether. The scheme began to collapse when an animal grower informed the government about the true content of Vitek's products and when investigators found undeclared substances concealed in a shipment from Pricor. Eventually a jury convicted Vitek and its president, Jannes Doppenberg, of conspiracy to defraud Customs and the FDA, of smuggling or receiving smuggled merchandise and of distributing adulterated or misbranded animal drugs with intent to defraud or mislead.

On appeal, Vitek and Doppenberg challenge several decisions of the district judge, beginning with his refusal to suppress the fruits of the government's search and ending with his application of the Sentencing Guidelines. The government also cross-appeals from the defendants' sentencing. We affirm in all respects.

I. Search and Seizure

The warrant authorizing the search of Vitek's premises permitted the seizure of (1) all tainted animal feed; (2) any and all misbranded drugs, to include clenbuterol and any of its derivatives; (3) any and all records from February 18, 1989, relating to the importation of merchandise and to the smuggling and illegal entry of tainted animal feed; and (4) any and all records from February 18, 1989, relating to the illegal entry and distribution of misbranded drugs in interstate commerce. The warrant further instructed that the evidence seized should indicate possible violations of 18 U.S.C. §§ 545 and 1001 and 21 U.S.C. § 331(a)—statutes prohibiting the smuggling and the distribution of misbranded drugs or adulterated food. The defendants assert the warrant lacked sufficient particularity and was not supported by probable cause. These are issues we review

de novo. *See United States v. Navarro*, 90 F.3d 1245, 1251 (7th Cir. 1996).

The Fourth Amendment requires that a warrant "particularly describ[e] the . . . things to be seized." This requirement precludes the issuance of a warrant that permits a "general, exploratory rummaging in a person's belongings," *Coolidge v. New Hampshire*, 403 U.S. 443, 467 (1971), and thereby ensures that the scope of a search will be confined to evidence relating to a specific crime that is supported by probable cause. *See United States v. Leary*, 846 F.2d 592, 600 (10th Cir. 1988). To satisfy the demand for particularity, a warrant "must describe the objects of the search with reasonable specificity, but need not be elaborately detailed." *United States v. Shoffner*, 826 F.2d 619, 630 (7th Cir. 1987) (quoting *United States v. Reed*, 726 F.2d 339, 342 (7th Cir. 1984)).

The Vitek warrant is broad, but not impermissibly so. *See United States v. Vanichromanee*, 742 F.2d 340, 347 (7th Cir. 1984) (warrant authorized seizure of writings related to the conspiracy to import heroin but did not specify precise documents); *Shoffner*, 826 F.2d at 630 (warrant authorized seizure of "stolen motor vehicles, parts of stolen motor vehicles . . . and documentation concerning the purchase, sale, ownership, titling and licensing of stolen motor vehicles"); *United States v. Pritchard*, 745 F.2d 1112, 1121 (7th Cir. 1984) (warrant authorized seizure of electronic wiretapping equipment, including electronic meter and devices resembling telephone receivers; agents executing warrant seized every portable electronic item within appellant's residence). This is not a case like *United States v. Spilotro*, 800 F.2d 959 (9th Cir. 1986), on which the defendants rely. In *Spilotro*, the search warrant's only limitation was that the items seized be evidence of a violation of any one of thirteen statutes, some of exceptional scope. *See id.* at 965 (noting that one of the statutes was 18 U.S.C. § 371, conspiracy to commit an offense against or defraud the government). The Vitek warrant, in contrast,

specified only three statutes and all are more narrowly focused than the statutes at issue in *Spilotro*.

The defendants argue that the warrant did not advise government agents how to distinguish between legal and illegal substances. But a warrant must explicate the items to be seized only as precisely as the circumstances and the nature of the alleged crime permit. *See Shoffner*, 826 F.2d at 630. With respect to the misbranded drugs and adulterated animal feed, we are unaware of any readily-discernable characteristic that would have enabled the agents to identify the illegal substances. This is not a case like *United States v. Fuccillo* or *Montilla Records of P. R., Inc. v. Morales*, in which warrants were deemed invalid because they failed to mention features that made the illegal products easily identifiable. *See Fuccillo*, 808 F.2d 173, 176-77 (1st Cir. 1987) (stolen clothing was made by a specific manufacturer); *Montilla Records*, 575 F.2d 324, 325 (1st Cir. 1978) (stolen records had a Motown label). Because the warrant could not have better informed the agents how to distinguish between legal and illegal substances, the instructions to seize "tainted animal feed" and "any and all misbranded drugs to include clenbuterol and any of its derivatives" were sufficiently particular.

In light of the nature of Vitek's crime, the instruction regarding the seizure of records also satisfied the requirements of the Fourth Amendment. Evidence of importing and distributing illegal substances is not likely to be confined to a single type of document. As the D.C. Circuit has noted, "specificity is even more difficult [when] evidence of the crimes can be found in almost every type of business document conceivable." *United States v. Dale*, 991 F.2d 819, 848 (D.C. Cir. 1993). Vitek and Doppenberg seek to analogize the Vitek warrant to the one in *United States v. Leary*, 846 F.2d 592 (10th Cir. 1988), but the warrants are distinguishable. In *Leary*, the warrant authorized the search of an export company and included two limitations: that any documents seized (1) "fall within a long list of business records typical of the documents kept by an ex-

port company," and (2) indicate a violation of the federal export laws. *Id.* at 600-01. The Tenth Circuit held that, in the context of a search of an export company, the *Leary* warrant placed no limitation on the government. *See id.* at 601. *Leary*, however, differs from the case at bar in at least two significant respects. First, unlike the Vitek warrant, the *Leary* warrant contained no date limitation. Second, and more importantly, in *Leary* the government had information that it could have used to particularize its description of the documents to be seized. *See id* at 604. As with the misbranded drugs and tainted animal feed, we are not convinced that the government could have been more precise about the records it was seeking. Vitek and Doppenberg suggest several ways the government might have tailored its warrant, such as directing agents to seize records that related to particular customers. But, as we elaborate below, the warrant here was supported by broad probable cause. All of the defendants' suggestions would have resulted in a warrant that was narrower than the probable cause supporting it. We are also skeptical of Vitek and Doppenberg's claim that, after the search, "[n]o records of any significance were left on the premises." Appellants' Br. at 25. The defendants' brief asserts that the agents seized material that filled approximately 100 banker's boxes; the record shows that agents seized approximately 20 boxes. *See* Tr. at 891. Indeed, Vitek had to produce additional documents in response to a grand jury subpoena. Because the warrant did not allow a dragnet seizure, and because the government could not have been more specific, the description of the records to be seized was sufficiently particular.

The warrant also was supported by probable cause. At the time the warrant was issued, the government had been informed that Vitek was importing and distributing animal feed tainted with clenbuterol. The government had also been informed that Pricor, Vitek's Dutch parent, was shipping tainted animal feed to other customers in the United States. In a shipment from Pricor to Vitek, investigators

had found hidden parcels containing oxytetracycline hydrochloride, colistine sufaat [sic], furaltadone hydrochloride and liquid Baytril. Sutherland Aff. at ¶ 30. All the drugs were misbranded and had not been declared on Customs documents. Based on these facts, the government had probable cause to believe that Vitek had been importing unapproved and mislabeled drugs. The government also had probable cause to believe that Vitek was blending these drugs into premixes and animal feeds. In sum, we find no reason to invalidate the warrant that authorized the search of Vitek's premises.

II. Evidentiary Issues

A. Prior Litigation in the Court of International Trade

The first of the defendants' evidentiary challenges relates to the charge that they conspired to defraud the Customs Service and the FDA, in violation of 18 U.S.C. § 371. To prove its case, the government argued, in relevant part, that the defendants failed to pay certain duties to Customs. But after earlier civil litigation with Vitek in the Court of International Trade, the government had stipulated that certain shipments from Pricor to Vitek were duty-free. In the criminal trial against Vitek and Doppenberg, the government argued that these same shipments were part of a scheme to defraud Customs. When Vitek sought to admit the government's prior stipulations, the district judge excluded this evidence pursuant to Federal Rule of Evidence 403, on the grounds that the stipulations would confuse the jury and cause undue delay. We review this ruling for an abuse of discretion. *See United States v. York*, 933 F.2d 1343, 1352, 1354 (7th Cir. 1991).

The government made its stipulations in the course of litigating *Vitek Supply v. United States*, 17 C.I.T. 111 (Ct. Int'l Trade 1993). In the events leading up to that case, Vitek had imported shipments of veal premix—or rather, what it declared to be veal premix—from Pricor. The Customs Service imposed a duty on these shipments on the theory that animal feed loses its duty-free status if it con-

tains vitamins and minerals that are suitable for human consumption. Vitek paid the duties under protest and then successfully challenged the policy of the Customs Service in the Court of International Trade. *See id.* After the court determined that the veal premix could enter the United States duty-free, Vitek sought a refund of the duties it had paid on other shipments that had been declared as veal premix. The government stipulated that these shipments were covered by the ruling of the Court of International Trade and granted the refund. During its criminal investigation, however, the government learned that its stipulations covered shipments that were in fact bulk vitamins, avoparcine and zinc bacitracin—not veal premix, as the government had been led to believe.

As the district judge recognized, admitting the government's stipulations into evidence would have opened the door to a panoply of issues surrounding the litigation in the Court of International Trade. In order to digest the import of the stipulations, the jury would have had to consider various Customs classifications, whether the information before the Court of International Trade was accurate and sufficient, and whether certain sworn statements were truthful. The nature of the questions addressed by the Court of International Trade would have only compounded the difficulty of the jury's task; the district judge candidly admitted that he did not "get a handle" on the documents the defendants sought to present to the jury until he had the benefit of oral argument. Tr. at 3642. This is not a simple case like *United States v. Fisher*, 106 F.3d 622 (5th Cir. 1997), on which Vitek and Doppenberg rely. In *Fisher*, the defendants sought to admit evidence that they had prevailed in an arbitration proceeding that involved an issue relating to their criminal prosecution. *See id.* at 633. The district court excluded the evidence under Rule 403 after the government objected on the grounds that the arbitrator had not detailed the reasons for the result and that the jury may not understand that it was not bound by the arbitrator's decision. *See id.* The court of appeals reversed,

explaining that the evidence went to the "heart of the case" and that the government could easily address its concerns during cross-examination. *See id.* In the case at bar, however, the district judge may have found himself presiding over a complex mini-trial that focused on the significance of the Court of International Trade's opinion and the actions the parties took in its aftermath. In light of these circumstances, the district judge did not abuse his discretion when he decided that admitting evidence of the government's prior stipulations would result in confusion and unnecessary delay.

As a practical matter, we also question whether the evidence would have benefitted Vitek and Doppenberg. They argue that the stipulations were important because the jury would question how the defendants could have deceived the Customs Service with respect to shipments that the government had stipulated were duty-free. But after the jury heard all the facts relating to the stipulations, they would perceive the defendants as trying to ride the coattails of an earlier, successful deception. We doubt that this would have given the jury reason to acquit the defendants of a charge of conspiracy to defraud the Customs Service.

B. Testimony of the Defense Expert

The defendants further contend that the district judge erred when he declined to allow a defense expert to testify about the effects of avoparcine and zinc bacitracin. Part of the government's case depended upon its proving that these substances are drugs. Under 21 U.S.C. § 321(g)(1)(C), a substance is a drug when it is intended to affect the structure or function of the body, and is not food. A defense expert allegedly was prepared to testify that avoparcine and zinc bacitracin do not affect the body's structure or function. The district judge did not allow the testimony because it was not sufficiently set forth in a summary the defendants submitted in response to a scheduling order. The defendants' summary stated, "[The expert] will testify

that avoparcine and zinc bacitracin are considered safe and effective as feed additives for calves and cattles." Vitek argues that it was "implicit" in this summary that the expert would testify that the substances are feed additives, not drugs. But neither the district court nor the government should have to parse the summary of expert testimony, searching for subtle nuances and relying on uncertain inferences. We agree with the district court that the summary failed to give adequate notice that the expert would testify that avoparcine and zinc bacitracin are not drugs.

It is well-established that in a civil case, a district judge has the discretion to exclude evidence as a means of sanctioning one of the parties for an inadequacy in its case, such as the summary at issue here. *See, e.g.*, *Mid-America Tablewares, Inc. v. Mogi Trading Co.*, 100 F.3d 1353, 1363 (7th Cir. 1996). In a criminal case, however, the district court's power to levy such sanctions is less unconstrained. Although "[f]ew rights are more fundamental than that of an accused to present witnesses in his own defense," *Taylor v. Illinois*, 484 U.S. 400, 408 (1988), the Supreme Court has allowed the imposition of sanctions when a criminal defendant has willfully violated a discovery order. *See id.* at 414. But it is not certain whether sanctions are permissible if the violation is not egregious—specifically, when "the excluded witnesses would undoubtedly have been at least somewhat helpful to the defense and violation of the [court's] order was not willful." *Tyson v. Trigg*, 50 F.3d 436, 445 (7th Cir. 1995); *see also United States v. Harvey*, 117 F.3d 1044, 1047-48 (7th Cir. 1997). Here, while the summary was sloppy and inadequate, it is not clear that the defendants intended to willfully violate the district court's order.

We have not yet had to define the limits of the district court's power to use the exclusion of evidence as a sanction in a criminal trial, *see Harvey*, 117 F.3d at 1047, and we need not decide that question today. If the district judge did err in excluding the expert's testimony, the error

was harmless. As previously explained, under 21 U.S.C. § 321(g)(1)(C), a substance is a drug if it is intended to affect the structure *or* function of the body. With respect to avoparcine, the expert's proffered testimony stated only that avoparcine did not have an effect on the *structure* of the body. The expert would not have stated that avoparcine did not affect the *function* of the body. *See* Tr. at 3515. Indeed, the expert would have testified that avoparcine was a dilution of an "antibiotic" used in "nutritive doses to improve animal performance." Tr. at 3515. We think this testimony supports the conclusion that avoparcine affects the function of the body and thus falls squarely within the definition of § 321(g)(1)(C). In regard to zinc bacitracin, the expert similarly would have referred to it as an antibiotic. *See* Tr. at 3518. And even if the expert's testimony had persuaded the jury that avoparcine and zinc bacitracin do not affect the structure or function of the body, § 321(g)(1)(C) is concerned with intended, not actual, effect. *See* 21 U.S.C. § 321(g)(1)(C) ("The term drug means . . . articles (other than food) *intended* to affect the structure or any function of the body. . . .") (emphasis added). The jury saw letters written by Doppenburg himself that (1) referred to avoparcine as "a growth promotant" used to "promote liver function," Gov.'s Ex. 357; (2) discussed "drugs . . . which work at the gut level (like Bacitracin[)]," Gov.'s Ex. 358; and (3) explained that "with . . . the FDA's crackdown on Zinc Bacitracin, the veal industry is . . . scared to lose all its (few) antibiotics," *id.* The expert's testimony would not have refuted the overwhelming evidence that the defendants intended avoparcine and zinc bacitracin to affect the structure or function of the body. Therefore, even if the judge erred in excluding the expert's testimony, his error was harmless.

C. The Daubert Hearing

At trial, an expert witness for the government testified that scientific testing had revealed that Vitek's premixes contained illegal substances. Vitek and Doppenberg main-

tain that this testimony is inadmissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). When a party challenges the admissibility of scientific testimony, we first conduct a de novo review to ensure that the district court followed the *Daubert* framework. *See Cummins v. Lyle Indus.*, 93 F.3d 362, 367 (7th Cir. 1996).

In *Daubert*, the Supreme Court determined that, when a district judge is faced with expert scientific testimony, the judge must decide "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." *Daubert*, 509 U.S. at 592; *cf.* Fed. R. Evid. 702. The Court set forth several factors that are "pertinent" to the district judge's determination whether testimony is scientifically valid: (1) whether the theory or technique can be and has been tested; (2) whether the theory or technique has been subject to peer review and publication; (3) whether the theory or technique has a known or potential rate of error; and (4) whether the theory or technique is generally accepted. *See Daubert*, 509 U.S. at 593-94. However, the Court emphasized that it did "not presume to set out a definitive checklist or test," *id.* at 593, and that the district judge's inquiry should be "flexible." *Id.* at 594.

Before allowing the government's expert to testify at trial, the district judge held a five-hour *Daubert* hearing to evaluate the scientific validity of the expert's testimony. Vitek and Doppenberg assert that the district judge strayed beyond the bounds of *Daubert* when he analyzed the material presented at the hearing. Specifically, they argue that the district court did not assess whether the expert's techniques were generally accepted, ignored error rates and placed undue emphasis on the qualifications of the government's expert.[1] We disagree.

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[1] In an argument that hardly merits discussion, the defendants contend that the district judge misapplied the concept of peer review. They argue that the district court decided that "there

(continued...)

We first address the contention that the district judge failed to determine whether the techniques used to ascertain the content of Vitek's premixes are generally accepted. All the chemical testing took place at a FDA laboratory, where analysts performed four procedures—fourier transform infrared spectrometry, gas chromatography/mass spectrometry, high performance liquid chromatography and electrospray liquid chromatography tandem mass spectrometry. Each of these procedures reveals a substance's "spectrum" or "fragmentation pattern"—a sort of chemical fingerprint. Analysts then identify a substance by comparing its spectrum with spectra from known standard samples or from a computer library. These procedures, and the tools used to perform them, are widely used and generally accepted in the fields of analytical and forensic chemistry. *See* Tr. at 2593-94, 2603, 2606, 2613. Vitek and Doppenberg, however, argue that the district court did not inquire whether the procedures are generally accepted for the specific purpose of determining the content of animal feed. But we have suggested that when tests involve the application of well-known instruments "to a particular and not-out-of-the-ordinary application," some of the *Daubert* factors may be worthy of less emphasis. See *Cummins*, 93 F.3d at 367 n.2. Because the FDA's testing procedures were not dependent on "abstract or novel scientific theory," *id.*, and because of the controls discussed below, the district court did not err by failing to focus on the narrow question whether the procedures were generally accepted as means of ascertaining the content of animal feed.

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[1] (...continued)
must have been peer review since the testing took place over the course of many months." Appellants' Br. at 46. However, review of the district judge's oral comments makes clear that he believed that there had not been enough time for extensive peer review. And because the tests used well-established technology to detect the presence of unapproved substances, the district judge felt that peer review was less critical. *Daubert* encourages exactly this kind of flexibility.

The defendants further argue that the district court should not have allowed the government's expert to testify because he was unable to identify the error rate of his testing methods. But the purpose of an inquiry into error rates is to determine whether tests are accurate and reliable. *See United States v. Pierre*, 47 F.3d 241, 243 (7th Cir. 1995). Here the district court heard evidence that the analysts controlled for false positives with "blanks" (samples known to contain none of the relevant chemical) and for false negatives with "spiked samples" (samples known to contain a specific amount of the chemical). Depending on the circumstances, this may be an appropriate means of ensuring both reliability and accuracy. *See id.* ("[P]erhaps [to test the reliability of a laboratory], the government submits an assortment of samples containing different drugs (and the statistically appropriate number of samples known not to be contaminated) to see how well the lab distinguishes among them."). The same sample was also submitted to multiple procedures by different analysts to ensure that the result was accurate. In light of these controls, the district judge found that "while the plaintiff's chemists may not have used every standard possible to control and test the operation of their techniques, they did employ proper standards." Tr. at 2727. We agree that there was ample evidence for the district judge to conclude that the government's tests were accurate and reliable.

With respect to the defendants' argument that the district court gave undue emphasis to the expert's qualifications, it is true that the court misspoke when it stated that one of the "nonexclusive guideposts" set forth in *Daubert* is whether the expert is qualified. Tr. at 2725. In fact, *Daubert* did not include the expert's qualifications in its list of pertinent considerations. *Daubert*, however, did not intend to set forth "a rigid or exclusive list." *See United States v. Hall*, 93 F.3d 1337, 1341 (7th Cir. 1996). And we have no doubt that an expert's qualifications bear upon the scientific validity of his testimony. In *United States v. Benson*, 941 F.2d 598 (7th Cir. 1991), we stated, "An expert's

opinion is helpful only to the extent the expert draws on some special skill, knowledge, or experience to formulate that opinion; the opinion must be an *expert* opinion (that is, an opinion informed by the witness' expertise) rather than simply an opinion broached by a purported expert." *Id.* at 604. Because an expert's qualifications bear upon whether he can offer special knowledge to the jury, the *Daubert* framework permits—indeed, encourages—a district judge to consider the qualifications of a witness. *Cf. Braun v. Lorillard Corp.*, 84 F.3d 230, 234-35 (7th Cir. 1996) (determining that jury could not hear testimony that plaintiff's lung tissue contained asbestos fibers, when purported expert was not experienced in the testing of human tissue and spent 99.9 percent of his time engaged in administrative and marketing activities for his consulting firm). Despite the district judge's inaccurate statement about *Daubert*, the district judge did not err when he gave weight to the expert's qualifications.

When the district court's analysis is within the parameters of *Daubert*, we affirm its decision to admit scientific evidence unless the decision is manifestly erroneous. *See Cummins*, 93 F.3d at 367. Here we find no such error. As we have explained, the district judge had reason to believe that the government's tests were reliable and accurate. The defendants argue that the district court did not give adequate weight to their expert, who testified at the *Daubert* hearing that the government had not properly validated its testing methodology. But, as the district judge noted in his oral ruling, the government's analysis was qualitative, not quantitative—that is, the government only needed to establish that an unapproved substance was present; it did not need to determine *how much* of the substance was present. *See* Tr. at 2726. The validation methods recommended by the defendant's expert were necessary only for a quantitative analysis. Moreover, the defense expert had little "hands-on" experience with the testing methodologies used to determine the content of Vitek's premixes. In sum, the district judge's oral ruling makes clear that he pon-

dered the testimony given at the *Daubert* hearing, evaluated it within the parameters of *Daubert* and concluded that the government's evidence was scientifically valid. He did not err in doing so.

III. Jury Instructions

Counts Seven, Nine, Eleven, and Twelve of the indictment charged Vitek and Doppenberg with introducing misbranded drugs in interstate commerce in violation of 21 U.S.C. § 333(a)(2). Counts Eight and Ten charged the defendants with introducing adulterated drugs in interstate commerce, also in violation of § 333(a)(2). The indictment specified that the drugs were "adulterated" because they were "new animal drugs"—they had not been approved by the FDA and recognized as safe and effective for their intended use of promoting growth and feed efficiency in veal calves. In order to be guilty of Counts Seven-Twelve, the defendants had to have acted with "intent to defraud or mislead." 21 U.S.C. § 333(a)(2). To act with this intent, Vitek and Doppenberg must have had "knowledge of the essential nature of the alleged fraud." *United States v. Hiland*, 909 F.2d 1114, 1128 (8th Cir. 1990).

Vitek and Doppenberg argue that the district court failed to instruct the jury that the government was required to prove such knowledge.[2] The district court charged the jury, in relevant part,

> To act with intent to defraud means to act voluntarily and intentionally to deceive or cheat. The intent to

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[2] The defendants also contend that the district court should have instructed the jury that 21 U.S.C. § 333(a)(1), which does not require intent to defraud or mislead, is a lesser included offense of § 333(a)(2). But this argument does not warrant discussion, since the defendants did not request an instruction on lesser included offenses until after the government began its closing argument. Accordingly, the request was untimely and the district court had the discretion to reject it. *See* Fed. R. Crim. P. 30; *United States v. Watson*, 894 F.2d 1345, 1349 (D.C. Cir. 1990).

> defraud may be established by proof that, with respect to the specific count in question, the defendant intended to deceive or cheat another person, a business entity, or a government agency. To act with intent to defraud a government agency means to act with the intent to interfere with or obstruct a lawful government function by deceit or trickery, or at least by means that are dishonest. . . .
>
> To act with the intent to mislead means to act voluntarily and intentionally to conceal a material fact and thereby create a false impression, or to omit or withhold information from a statement and thereby cause a portion of the statement to be misleading. An intent to mislead may be established by proof that the defendant intended to mislead a person, an entity with whom he was doing business, or a government agency.

Our review of these instructions "is limited to the determination of whether the jury was misled in any way and whether it had understanding of the issues and its duty to determine these issues." *United States v. Dack*, 987 F.2d 1282, 1284 (7th Cir. 1993) (internal quotation marks and citations omitted). In making this determination, we consider how the jury perceived the instructions in light of all the evidence and arguments presented at trial. *See EEOC v. AIC Sec. Investigations, Ltd.*, 55 F.3d 1276, 1283 (7th Cir. 1995). We reverse only if "the jury's comprehension of the issues is so misguided that it prejudiced the complaining party." *Dack*, 987 F.2d at 1284.

Given the allegations against Vitek and Doppenberg, the government needed to show that the defendants: (1) knew they were distributing a "new animal drug"; and (2) knew their labeling omitted any mention of unapproved substances. *See Hiland*, 909 F.2d at 1128; *United States v. Industrial Lab. Co.*, 456 F.2d 908, 910 (10th Cir. 1972). Here the district court's instructions, when considered in their larger context, adequately advised the jury of these requirements. The district judge gave comprehensive instructions regarding the definition of "new animal drug,"

making clear that the term refers to a drug that is not approved by the FDA and not recognized as safe and effective for its intended use. *See* Tr. at 4072. The judge also defined "misbranded." *See* Tr. at 4070. And while the instructions regarding the definition of "act with intent to defraud or mislead" did not explictly state that the defendants had to know that they were distributing new animal drugs or misbranded products, the instructions were given on the heels of closing arguments that were replete with references to the defendants' knowledge. For example, the defendants' counsel cautioned the jury, "[U]nless you can say beyond a reasonable doubt we think these folks knew exactly what was required and exactly what was prohibited, then you should not be entering . . . a verdict that they engaged in schemes to defraud, or did certain things with the intent to defraud." Tr. at 3999-4000. The prosecutor also made repeated references to Doppenberg's knowledge. *See, e.g.*, Tr. at 3839-40 (referencing letters presented at trial and asserting that they showed Doppenberg knew the illegality of avoparcine, zinc bacitracin and nitrofurazone); Tr. at 3847 (urging that when Doppenberg spoke with government investigators, he knew certain substances were illegal); Tr. at 4035 (asking rhetorically whether Doppenberg thought certain substances were food instead of drugs). In light of these closing arguments and the evidence presented at trial, the jury understood that one of the issues was whether Vitek and Doppenberg *knew* that they were distributing "new animal drugs" and that their labeling omitted information about the presence of unapproved substances. And finally, as a practical matter, the guilty verdict on the charge of conspiracy against the FDA and Customs is a "clear indication" that the jury believed that Vitek and Doppenberg were aware of the illegal nature of their activities. *See Hiland*, 909 F.2d at 1129.

IV. Sentencing

After four days of hearings, the district judge sentenced Doppenberg to 44 months of imprisonment for conspiring

to defraud the FDA and Customs and for smuggling and receiving smuggled merchandise (Counts One-Six), and to 36 months of imprisonment for introducing misbranded and adulterated drugs into interstate commerce (Counts Seven-Twelve), to run concurrently. Doppenberg also received three years of supervised release for Counts One-Six, and one year of supervised release for Counts Seven-Twelve, also to run concurrently. In addition, he was ordered to pay a special assessment of $600 and a fine of $25,000. Vitek was placed on probation for four years and fined $350,000. Both defendants, and a co-conspirator who pleaded guilty, were made jointly liable for a restitution payment of $735,266.65. Of this amount, $29,452.65 was for duties owed to the Customs Service; the remaining $705,814 was for a meat processor that destroyed its calves upon learning that they had been fed Vitek's tainted products.

These sentences satisfy neither the defendants nor the government. Both appeal from the court's application of U.S.S.G. § 2F1.1, which captures the "intended, probable, or otherwise expected loss" from a defendant's fraud. *United States v. Schneider*, 930 F.2d 555, 558 (7th Cir. 1991). The defendants argue that the losses of the meat processor should not count toward the § 2F1.1 calculation and that all of Vitek's shipments were duty-free under *Vitek Supply Co. v. United States*, the decision rendered by the Court of International Trade. For its part, the government asserts that the district court erred when, in applying § 2F1.1, it rejected evidence of competitor and consumer losses. After considering these arguments, we are satisfied that the district judge meted out appropriate sentences.

A. The Defendants' Arguments

Vitek and Doppenberg contend that, for purposes of § 2F1.1, Swissland, the meat processor, has not suffered a "loss" and is not a "victim." The definition of these two

terms is a question of law that we review de novo. *See United States v. Barrett*, 51 F.3d 86, 89 (7th Cir. 1995). As an initial matter, we reject the contention that Swissland has not incurred a "loss" within the meaning of § 2F1.1. After the FDA became aware that Swissland's herds had ingested a banned nitrofuran, Swissland sought assurance that the FDA would not initiate an enforcement action if Swissland sold the meat from its calves. The FDA refused to provide such an assurance but did not order Swissland to destroy the meat. Instead the FDA informed Swissland that it was free to pursue judicial resolution of the issue, and that any decision to destroy the meat "would be purely voluntary." Defs.' Sup. Sent. Mem., Ex. G3. Anxious to capitalize on the FDA's selection of an adjective, the defendants argue that the decision to destroy the meat was voluntary because Swissland could have argued in court that the meat was safe for human consumption and that the FDA misconstrued the applicable regulations. The defendants then cite *United States v. Marlatt*, 24 F.3d 1005 (7th Cir. 1994), for the principle that the "voluntary decision to take a loss, even if reasonable in terms of business strategy, does not result in legal liability for the defendant under § 2F1.1(b)(1)." Appellants' Br. at 62. The defendants' argument fails for at least two reasons. First, we would not use the word "voluntary" to describe the choice between destroying meat and judicially challenging a federal agency's interpretation of its regulations. Second, and more fundamentally, the defendants have misunderstood *Marlatt*. That case distinguishes between direct and consequential damages, *see Marlatt*, 24 F.3d at 1007, and reiterates the unsurprising requirement that a defendant must have legally caused a loss before he can be held accountable for it, *see id.* at 1006. But *Marlatt* does not hold that the cost of measures to rectify harm caused by the defendant (here the ingestion of an unapproved substance by Swissland's herds) falls outside the purview of § 2F1.1, when those measures may (in some perverse way) be considered voluntary.

We also reject the assertion that Swissland was not a victim for purposes of § 2F1.1. As Vitek and Doppenberg point out, Swissland was not a victim unless it was in fact defrauded—i.e., unless it did not know that Vitek's product contained a banned nitrofuran. To bolster their claim that Swissland was a knowing consumer of Vitek's tainted product, the defendants rely on the law of agency.[3] In *Barrett* we suggested that, under § 2F1.1, the knowledge of an agent is imputed to the agent's employer when the agent is acting at least in part for the benefit of the employer. *See* 51 F.3d at 89 (quoting *United States v. One Parcel of Land*, 965 F.2d 311, 316 (7th Cir. 1992)). Vitek and Doppenberg argue that the knowledge of Dr. Dan Shields should be imputed to Swissland. The contention is that Shields is the vice-president of American Feeds and Livestock (AF&L), the animal feed company that Swissland employed to recommend feeds and feed additives. There is no question that Shields knew that Vitek's product, dubbed "Apple First Start," contained nitrofurans; indeed, Shields helped Doppenberg develop the product. According to the defendants, Shields encouraged Swissland to use Apple First Start because it prevented scours; thus Shields was "acting for the benefit" of Swissland and his knowledge is imputed to the meat processor.

The defendants gloss over several points that distinguish Shield's connection with Swissland from the straightforward employer/agent relationship discussed in *Barrett*. Shields was not a simple agent of Swissland. Instead, he was the employee of one of Swissland's independent contractors. As a general matter, an employer is less likely to be held vicariously liable for the acts of its independent contractors than for the acts of its employees. *See* Stephan D. Sugarman, *A Restatement of Torts*, 44 Stan. L. Rev.

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[3] The defendants also argue that circumstantial evidence established that Swissland knew the true content of Vitek's products. The district judge, however, was convinced that Swissland had been defrauded. Because we do not find this conclusion clearly erroneous, we do not further discuss the circumstantial evidence.

1163, 1195 (1992). But it is not necessary for us to determine the import of AF&L's independent contractor status, as there is yet another factual complication which convinces us that Shields' knowledge cannot be imputed to Swissland. Shields had his own feed supply business, Fancy Calf, which was unconnected to AF&L and was not an independent contractor of Swissland. Fancy Calf, not AF&L, purchased Apple First Start from Vitek. Thus, strictly speaking, we cannot say that Swissland received Apple First Start from one of its independent contractors. And Shields was simply wearing too many hats—co-creator of Apple First Start, vice-president of AF&L, and proprietor of Fancy Calf—for us to impute his knowledge to Swissland with any degree of confidence about the fairness of the result. We therefore affirm the district court's decision to include Swissland's $705,814 loss in the § 2F1.1 calculation.

In applying § 2F1.1, the district court also included a $29,452.65 loss suffered by Customs. Vitek and Doppenberg, however, argue that under the decision rendered by the Court of International Trade, *Vitek Supply Co. v. United States*, 17 C.I.T. 111 (Ct. Int'l Trade 1993), Vitek's shipments were duty-free. Therefore, the defendants contend, although Customs was defrauded, it incurred no loss. But the defendants' interpretation of *Vitek* is untenable. *Vitek* explained that, in order for a shipment to be duty-free under the applicable regulation, it must be a preparation used in feeding animals and contain at least six percent grain product. *See id.* at 112. The remainder of the preparation must consist of feedstuffs—sources of nutrition. *See id.* at 114. The unapproved substances in Vitek's premixes were not sources of nutrition. Accordingly, Vitek's shipments are dutiable and Customs has indeed suffered a loss within the meaning of § 2F1.1.

B. The Government's Cross-Appeal

At sentencing, the government asked the district court to include the losses of Vitek's competitors and downstream

consumers in its § 2F1.1 calculation. The district court refused to do so because it would "involve too much conjecture and speculation" and "the evidence in this case is [in]sufficient [to provide] a firm foundation for such a finding." Sen. Tr. at 210. While we review the definition of "loss" de novo, we review the district court's factual determination regarding losses for clear error. *See United States v. Andersen*, 45 F.3d 217, 220 (7th Cir. 1995).

With respect to competitor losses, the government first looked to other sellers of premixes for veal calves—Vitek's direct competitors. The government assumed that these sellers suffered losses when feed companies and livestock growers purchased Vitek's tainted premixes, and sought to use Vitek's gain from its premix sales as a proxy for that loss. This approach is not without support; the application notes to § 2F1.1 allow a district court to use the defendant's gain to calculate a victim's loss when a more precise measure is unavailable. *See* U.S.S.G. § 2F1.1, comment (n.8); *Andersen*, 45 F.3d at 221. But gain may be used only if "there is in fact a loss, and [the] use of the gain results in a 'reasonable estimate of the loss.'" *Andersen*, 45 F.3d at 221 (quoting U.S.S.G. § 2F1.1 comment (n.8)). We agree with the district judge that, in this case, the government has not presented sufficient evidence to allow us to determine whether the criteria set forth in *Andersen* are satisfied. And even if the government had proved the existence of a loss, and that Vitek's gain was a reasonable estimate of that loss, the government has not proved that Vitek's sale of unadulterated products *caused* the loss.

The government has done nothing more than establish the mere fact that other companies sell premix. *See* Gov.'s Sent. Mem. at 7 (citing to an exhibit that refers to Qualitech, another premix company). It is true, as the government argues, that in *Andersen* we declined to find a loss because we had no reason to believe that competitors were selling the same or similar products. *See* 45 F.3d at 221. But whether the defendant has competitors is the beginning, not the end, of the inquiry. Here, while there is proof

that some customers knew the content of Vitek's products, there is no evidence that the presence of illegal ingredients drew customers to Vitek from its competitors. And even if we assume that Vitek's competitors suffered a degree of loss—that at least some of Vitek's customers would have gone elsewhere had Vitek's premixes not contained illegal substances—the government has provided us with no means of determining whether Vitek's gain is a reasonable estimate of that loss. Vitek's conduct was not pervasively illegal; it sold legal products as well as illegal ones. We have every reason to believe that if Vitek had not sold illegal premixes, it would have sold similar, legal products. Presumably, then, in the absence of Vitek's fraud, not all of its sales would have gone to other sellers. On the record before us, however, we have no method of estimating how many sales would have gone elsewhere. For example, we do not know how many competitors Vitek has. We do not know the market shares of any of its competitors, or, for that matter, Vitek's market share for its illegal or legal products. We do not know whether purchasers of feed additives frequently change suppliers. In sum, we cannot even begin to determine whether Vitek's gain was a reasonable estimate of its competitors' losses. The district judge did not err when he refused to use Vitek's gain as a proxy for the losses of its direct competitors.

The government also asserts that the district judge should have included the losses of another class of "competitors": upstream drug suppliers. There are legal drugs that promote growth and feed efficiency in veal calves and prevent scours. The manufacturers of these drugs competed with Pricor, Vitek's Dutch parent. The government argues (and this is ironic, in light of our preceding discussion) that, if Vitek had not included unapproved substances in its premixes, it would have included similar, legal substances. Therefore, the government contends, upstream drug suppliers suffered a loss as a result of Vitek's illegal activities. *See* Gov.'s Sent. Mem. at 6-7 and Ex. A. The government again proposed using Vitek's gain as a

measure of these upstream losses; to this end, the government determined how much Vitek "marked up" the drugs it included in its premixes. In support of the theory that the district court should use Vitek's gain as proxy for upstream losses, the government submitted a publication entitled "1993 Feed Additive Compendium," which establishes that approved drugs serve the same purposes as the drugs used by the defendants. The government also submitted evidence that Vitek purchased one legal substance from Pfizer, Inc. But we have no means of estimating, among other things, whether Vitek's mark-up on illegal substances is equivalent to the mark-up on legal substances. We do not know whether Vitek could have obtained some, or all, of the legal drugs from its parent company. As with direct competitors, the government simply has failed to provide evidence that enables us to determine the extent of upstream losses and whether Vitek's gains are a reasonable measure of these losses.

Finally, the government argues that the § 2F1.1 calculation should include the losses of downstream consumers. Unlike Swissland, most of Vitek's direct customers were aware that the premixes contained unapproved drugs. Therefore, as the government concedes, these customers were not defrauded and the defendants cannot be held liable for their losses. However, the government argues, at some point innocent purchasers consumed the meat of veal that had been treated with Vitek's tainted products. The government contends that these innocent purchasers suffered a loss, which should be measured by Vitek's gross sales of its tainted products.

This was the approach taken in *United States v. Marcus*, 82 F.3d 606 (4th Cir. 1996). In *Marcus*, the defendant conspired to defraud the FDA by failing to notify or seek approval for a drug he modified to treat a heart condition. *See id.* at 607. The defendant's gross sales from the unapproved drug were more than ten million dollars. In determining that consumers had suffered a loss, the Fourth Circuit reasoned

> The marketing of a drug employing an unapproved and untested formula, when the modification presents the potential to affect the safety, therapeutic value, or bioequivalence of the drug, renders the drug of unknown efficacy and safety; the sale of a drug represented to possess FDA approval under those circumstances does not provide consumers with the benefit of their bargain . . . . Given the unchallenged finding that consumers would not purchase a drug of unknown safety and efficacy at any price, the district court correctly concluded that . . . gross sales were the appropriate measure of the actual loss suffered by consumers. . . .

Id. at 610. As this quotation indicates, the Fourth Circuit's reasoning rests largely on the assumption that a knowing consumer would not pay *anything* for the product that the *Marcus* defendant sold.

In some cases, a product may be so inherently harmful that a court can confidently conclude that it is worthless. At oral argument, the government stated that knowing consumers would have left the meat from veal treated with Vitek's products "rotting on the shelves." Perhaps the government is correct. But perhaps it is not. People take a wide variety of health risks; for instance, the knowing ingestion of certain carcinogens can be considered almost commonplace. Maybe some purchasers would have risked consuming the meat. If so, the proper measure of the consumer's losses would be the difference between what the consumer would have paid if she had all the facts, and the price the consumer actually paid. *Cf.* U.S.S.G. § 2F1.1 app. n.7(a). The problem, of course, is that these issues can only be addressed by speculation. This is not a case like *Marcus*, where the district court made an unchallenged finding that consumers would not purchase the defendant's product at any price.

We do not wish to minimize the conduct of Vitek and Doppenberg. The government's basic proposition is correct: innocent purchasers did not receive the benefit of the bargain when they purchased meat from veal calves treated

with Vitek's premixes. As we explained in *Andersen*, "The FDA is in the business of protecting the public . . . . [T]he defendants . . . caused harm to the public through their violations of FDA rules." 45 F.3d at 222. We also suggested that the district court may wish to consider making an upward departure to account for "non-monetizable risk to human and animal health."[4] *Id.* But the district court cannot punish the defendants for this harm by including speculative losses in its § 2F1.1 calculation. Accordingly, the sentences of Vitek and Doppenberg, and their underlying convictions, are AFFIRMED.

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[4] Here the district court denied the government's request for such a departure. The government did not appeal from this ruling.

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APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

June 16, 1998

Before

Hon. Richard D. Cudahy, Circuit Judge
Hon. John L. Coffey, Circuit Judge
Hon. Terence T. Evans, Circuit Judge

Nos. 97-1254, 97-1255 & 97-1498

UNITED STATES OF AMERICA,
Plaintiff-Appellee, Cross-Appellant

v.

VITEK SUPPLY CORPORATION, and,
JANNES DOPPENBERG,
Defendants-Appellants, Cross-Appellees.

ORDER

The defendants-Appellants have filed a petition for rehearing. Upon consideration, no member of the panel wished to rehear the case.

Accordingly, the petition of the defendants-appellants is DENIED.

Supreme Court, U.S.
FILED
JAN 13 1999
CLERK

(2)

No. 98-447

In the Supreme Court of the United States

OCTOBER TERM, 1998

VITEK SUPPLY CORPORATION AND
JANNES DOPPENBERG, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the district court's instructions adequately advised the jury of the elements of petitioners' offenses.

2. Whether the district court had discretion to reject petitioners' untimely lesser-included-offense instruction.

3. Whether the district court's finding that petitioners' customer had been defrauded, and had therefore suffered a loss cognizable under United States Sentencing Guidelines § 2F1.1, was clearly erroneous.

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BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A) is reported at 144 F.3d 476.

JURISDICTION

The judgment of the court of appeals was entered on May 14, 1998. A petition for rehearing was denied on June 16, 1998 (Pet. App. B). The petition for a writ of certiorari was filed on September 14, 1998. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial, petitioners were convicted on one count of conspiring to defraud the United States by impeding the lawful functions of the United States

Food and Drug Administration and the United States Customs Service, in violation of 18 U.S.C. 371; five counts of smuggling goods into the United States, in violation of 18 U.S.C. 545; and six counts of introducing adulterated and misbranded drugs into interstate commerce, in violation of 21 U.S.C. 331(a), 333(a)(2), and 352(a). Petitioner Doppenberg was sentenced to 44 months' imprisonment, to be followed by three years' supervised release, and was fined $25,000. Pet. App. A17-A18; see also C.A. App. 2-4.[1] Petitioner Vitek Supply Corporation was placed on four years' probation and was fined $350,000. Pet. App. A18; C.A. App. 8-9. Petitioners were held jointly liable for restitution of $735,266.65. Pet. App. 18; see C.A. App. 6, 11. The court of appeals affirmed. Pet. App. A1-A26.

1. Section 331(a) prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. 331(a). Under Section 333(a)(2), a person who violates Section 331 "with the intent to defraud or mislead" is subject to criminal penalties. 21 U.S.C. 333(a)(2).

Petitioner Vitek Supply Corporation, of which petitioner Doppenberg was the general manager, manufactured feed mixtures for veal calves using certain substances that were unapproved by the Food and Drug Administration. Pet. App. A1; Gov't C.A. Br. 6. Several of those substances are carcinogenic or otherwise harmful to human health. Pet. App. A1. With the assistance of Vitek's Dutch parent corporation, petitioners

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[1] "C.A. App." refers to the appendix materials filed in the court of appeals, some of which were appended to petitioners' opening brief, and some of which were filed in a "Separate Appendix of Defendants-Appellants."

smuggled the substances into the United States, often through fraudulent means. *Id.* at A2. The evidence of fraud included the use of code names and numbers in inventory records, mixing formulas, invoices, and other records; misrepresenting to U.S. Customs the contents of goods imported into the United States; concealing goods on pallets underneath other goods; double-bagging products to conceal the labeling; and identifying on product labels all contents except the illegal drugs. Gov't C.A. Br. 43-44.

2. At trial, the district court charged the jury that, with respect to the scienter component of Section 333(a)(2),

> [t]o act with intent to defraud means to act voluntarily and intentionally to deceive or cheat. The intent to defraud may be established by proof that, with respect to the specific count in question, the defendant intended to deceive or cheat another person, a business entity, or a government agency. To act with intent to defraud a government agency means to act with the intent to interfere with or obstruct a lawful government function by deceit or trickery, or at least by means that are dishonest.
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> . . .
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> To act with the intent to mislead means to act voluntarily and intentionally to conceal a material fact and thereby create a false impression, or to omit or withhold information from a statement and thereby cause a portion of the statement to be misleading. An intent to mislead may be established by proof that the defendant intended to mislead a person, an entity with whom he was doing business, or a government agency.

Pet. App. A15-A16. The court rejected other instructions submitted by petitioners, which would have described the scienter element in more detail—by specifying, for example, that the government had to prove that petitioners "knew that the substances in question were new animal drugs" and that petitioners had "actual knowledge that the drug[s] at issue w[ere] unapproved and not properly labeled or safe." Gov't C.A. Br. 45-46; see generally C.A. App. 126-134.

At the very close of the charging conference, petitioner Doppenberg's attorney orally announced, without elaboration, that "on behalf of Mr. Doppenberg we want lesser included offenses to be submitted to the jury." Tr. 3835. The district court rejected the request on the ground that "[i]f you wanted that you should have brought it up before." *Ibid.* Petitioners subsequently put into writing their proposal for a lesser-included-offense instruction on the Section 333(a)(2) counts, but only after the government had begun its closing argument. See Gov't C.A. Br. 41-42; Pet. App. A15 n.2; see also C.A. App. 121-123. The district court again rejected the proposed instruction, this time on two independent grounds: first, that the request was untimely and, second, that it was insufficiently detailed to enable the court "to determine whether or not [the purported lesser included offenses] are in fact lesser included offenses." C.A. App. 125; see also Pet. App. A15 n.2.

Petitioners were found guilty on all twelve counts of the indictment. C.A. App. 1, 7. In calculating the offense level for the six adulterated and misbranded drug counts, the district court applied the specific offense characteristic in Section 2F1.1(b)(1) of the United States Sentencing Guidelines for losses greater than $2,000. Pet. App. A17-A18. The district court arrived

at a loss figure that fell between the figures suggested by the government and petitioners. The figure adopted by the court was based on the sum of the government's own loss of $29,254 in import duties plus a $705,814 loss incurred by a meat processing company (Swissland Packing Co.), which had to destroy its calves after learning that they had been fed tainted products supplied by petitioners. *Id.* at A18; see C.A. App. 38.[2]

3. The court of appeals affirmed. Pet. App. A1-A26. After addressing a variety of issues that petitioners do not present here (see *id.* at A2-A15), the court turned to petitioners' challenge to the district court's scienter instructions. The court of appeals held that those instructions, "when considered in their larger context, adequately advised the jury" of the requirements of Sections 331(a) and 333(a)(2). *Id.* at A16; see *id.* at A15-A17. The court separately held that petitioners' challenge to the district court's refusal to present a lesser-included-offense instruction "does not warrant discussion," because petitioners' request for that instruction was "untimely," and "the district court had the discretion to reject it." *Id.* at A15 n.2.

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[2] In early December 1998, petitioners agreed to make immediate payment of $400,000 "for the use and benefit of Swissland" as "payment in full of the restitution ordered to be paid to Swissland" in the district court judgment. Settlement Agreement and General Releases at 4; see also Order of Dec. 8, 1998 (approving settlement agreement). The parties entered into that settlement agreement largely because Swissland wished to avoid "additional efforts to locate assets and supplemental litigation to enforce collection." Settlement Agreement at 2. The United States was a party to the agreement "only because the aforesaid restitution is to be paid to the U.S. for the use and benefit of Swissland." *Id.* at 3. Petitioners have not contended, and could not contend, that the settlement agreement is in any respect relevant to the issues presented in this petition.

Finally, as to sentencing, the court of appeals rejected challenges brought by both the government and petitioners to the district court's calculation of the amount of loss under Guidelines § 2F1.1. Pet. App. A17-A26. The court of appeals found, among other things, that the district court had not erred in rejecting petitioners' claim that Swissland had known "the true content" of petitioners' products and therefore (according to petitioners) could not have suffered any cognizable "loss." *Id.* at A20 n.3.

ARGUMENT

1. Petitioners first contend (Pet. 15-21) that the district court erred in rejecting their proposed scienter instructions for the substantive offenses charged under Section 333(a)(2), and that the court of appeals' refusal to reverse their convictions in light of that purported error raises important issues concerning the harmless error doctrine. That claim is without merit, because there was in fact no "error" that could give rise to any harmless error issue.

As the court of appeals determined, the instructions actually given, "when considered in their larger context, adequately advised the jury" of the nature of the required scienter finding. Pet. App. A16-A17.[3] Peti-

[3] Petitioners are therefore simply mistaken in contending (Pet. 17) that the court of appeals "acknowledged that the district court's instructions failed to include * * * necessary elements of the offenses charged." Although the court of appeals noted that the instructions "did not explicitly state that the defendants had to know that they were distributing new animal drugs or misbranded products," it found no error, because, taking the instructions as a whole and in context, "the jury understood that one of the issues was whether [petitioners] *knew* that they were distributing 'new animal drugs' and that their labeling omitted information about the presence of unapproved substances." Pet. App. A17. In any event,

tioners contend (Pet. 19) that the court of appeals erred in considering "the evidence and arguments of counsel" in assessing the jury instructions. This Court has made clear, however, that in determining whether there is "a reasonable likelihood that the jury has applied the challenged instruction[s]" erroneously, a court must consider the "commonsense understanding of the instructions in the light of all that has taken place at the trial." *Boyde* v. *California*, 494 U.S. 370, 380-382 (1990). The court of appeals correctly applied that guidance here. The court found that "[i]n light of the[] closing arguments and the evidence presented at trial," the jury understood the elements of the charged offenses and on that basis found petitioners guilty of committing those offenses. See Pet. App. A17. There was thus no constitutional violation of which petitioners could complain. As a result, unlike the harmless-error cases that petitioners cite (Pet. 18-19), this case does not present any issue concerning the appropriate scope of harmless error review when the trial court's jury instructions deprived the jury of its role in finding each element of a charged offense.

Although petitioners suggest (Pet. 20-21) that this case presents an opportunity for the Court to revisit the issue left unresolved in *Rogers* v. *United States*, 118 S. Ct. 673 (1998), that case in fact illustrates precisely why petitioners' claims here do not warrant review. In *Rogers*, this Court granted certiorari to consider whether a district court's failure to instruct the jury on an element of an offense could be harmless where the

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as the government stressed in the court of appeals, we believe that the district court's instructions, even if viewed in isolation, adequately described the scienter element of the offenses at issue. See Gov't C.A. Br. 45-48.

defendant had admitted the element under oath. The Court dismissed the writ as improvidently granted, however, after determining that the jury may in fact have construed the instructions to require it to find the purportedly omitted element. *Id.* at 676-677 (plurality opinion); *id.* at 677-678 (O'Connor, J., concurring in the result). Here, the court of appeals' correct and fact-bound determination that the jury knew (and found) the elements of petitioners' offenses renders irrelevant, as in *Rogers*, any inquiry into the circumstances in which an instructional error that removes an element from the jury's consideration requires reversal of the defendant's conviction.[4]

2. Petitioners next argue (Pet. 21-24) that the court of appeals should have considered on the merits their claim that they were entitled to a lesser-included-offense instruction on the Section 333(a)(2) counts. The court denied that claim on procedural grounds, reasoning that the district court had acted within its discretion in rejecting that instruction because the defendants did not request it in writing "until after the

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[4] This Court recently granted certiorari in a case presenting a harmless-error issue similar to the one that petitioners mistakenly contend is presented here. See *Neder* v. *United States*, No. 97-1985 (to be argued Feb. 23, 1999). Even if there had been error in this case, however, there would be no reason to hold the petition here pending disposition of *Neder*. This case, unlike *Neder*, would not require a harmless-error analysis based on the strength of the evidence on an uncontested issue. If there had been error in this case, harmless-error analysis would rest on, *inter alia*, the fact that the jury's "guilty verdict on the [separate] charge of conspiracy against the FDA and Customs is a 'clear indication' that the jury believed that Vitek and Doppenberg were aware of the illegal nature of their activities." Pet. App. A17; see, *e.g.*, *Carella* v. *California*, 491 U.S. 263, 270-271 (1989) (Scalia, J., concurring in the judgment).

government began its closing argument." Pet. App. A15 n.2. Petitioners nonetheless contend (Pet. 22) that petitioner Doppenberg's attorney adequately preserved their request for that instruction by announcing, at the end of the charging conference, that "we want lesser included offenses to be submitted to the jury." Tr. 3835. That claim is without merit.

Rule 30 of the Federal Rules of Criminal Procedure provides that parties shall file "written requests" for jury instructions by "the close of evidence." Petitioners violated that requirement. Indeed, the district court noted that the defense had engaged in a "pattern of * * * dilatory tactics," that "there weren't *any* instructions submitted in a timely fashion for the defendants," and that, although the court did accept some belated proposals, it "ha[d] to draw the line somewhere," for "otherwise the court would never be able to proceed to instruct the jury." C.A. App. 124 (emphasis added). In these circumstances, the district court acted well within its discretion in refusing to consider the proposed lesser-included-offense instruction.

Neither *United States* v. *Krapp*, 815 F.2d 1183, 1187 (8th Cir.), cert. denied, 484 U.S. 860 (1987), nor *United States* v. *Whitaker*, 447 F.2d 314, 317 (D.C. Cir. 1971), supports petitioner's erroneous contention (Pet. 24) that "an oral request for lesser-included offense or other instructions is sufficient to * * * preserve[] the request for appellate review," a proposition that is at odds with Rule 30. In neither *Krapp* nor *Whitaker* did the court of appeals clearly reverse a district court's decision to reject an instructional request on procedural grounds; in each case, the district court appeared to have considered and rejected the request on the merits, and the government then apparently raised the procedural issue on appeal. See *Krapp*, 815 F.2d at 1187;

Whitaker, 447 F.2d at 317. Moreover, neither decision purports to abrogate a district court's discretion to reject proposed jury instructions that are filed in violation of Rule 30's procedural requirements. Indeed, after observing that "Rule 30 evidences a preference for written requests for instructions," the *Krapp* court reaffirmed that "[a] failure to make a written request can under certain circumstances be sufficient grounds for denial of the requests." 815 F.2d at 1187. One such circumstance is where, as here, the defendant's oral request provides insufficient notice of or support for the proposed instruction.[5]

3. Finally, petitioners challenge (Pet. 25-31) the district court's determination that Swissland had been defrauded by petitioners' scheme and that it had therefore suffered a "loss" for purposes of § 2F1.1 of the United States Sentencing Guidelines. Petitioners argue that Swissland could not have been defrauded because, in their view, Swissland must have known about petitioners' illegal scheme. The court of appeals rejected that argument in a footnote, holding that the district court's determination "that Swissland had been defrauded" was not "clearly erroneous." Pet. App. A20 n.3. That factbound determination warrants no further

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[5] The district court cited the untimeliness of petitioner's request as one of two independent reasons for denying that request. The court also explained that "the request does not contain a detailed statement" supporting the proposed lesser-included-offense instruction—a statement necessary to help the court determine whether such an instruction was in fact warranted and, if so, how it should be framed. C.A. App. 125; cf. Gov't C.A. Br. 42-44. That procedural default would impose an independent obstacle to appellate relief even if petitioners could plausibly argue that the district court abused its discretion in rejecting their request as untimely.

review. Although petitioners contend (Pet. 28, 30) that the court of appeals' holding on this point is "directly in conflict" with precedents (including Seventh Circuit precedents) concerning the appropriate burden of proof in attributing "losses" to defendants, that is plainly incorrect. The court of appeals did not discuss any issue concerning burden of proof, but simply reviewed the evidence of "loss" under a standard of review appropriately deferential to the district court.[6]

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[6] Petitioners contend (Pet. 29) that, in the court of appeals, the government "conceded * * * that it had not affirmatively proven that [Swissland] was defrauded by the defendants." That is inaccurate. The government argued instead: "[Petitioners] acknowledge that there was no direct evidence establishing actual participation or even guilty knowledge on Swissland's part, but apparently feel that the government must produce affirmative evidence to demonstrate the negative. * * * The government submits that it meets its overall burden of proof by demonstrating loss to a third party caused by [petitioners'] crimes, together with the absence of any evidence that the third party knew of the crime and accepted its benefits." Gov't C.A. Br. 55 (citation omitted). The court of appeals did not address the parties' dispute on that issue.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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